

Remarks

Claims 1-76 are pending in the current patent application. Before addressing the office action on the merits, Applicant would like to thank the Examiner for meeting with Applicant's attorney on January 20, 2006.

As discussed in the interview, all the Claims were accounted for in the election/restriction requirements on page 2 of the office action mailed on November 18, 2005 except Claims 74-76. Examiner agreed in the interview that Claims 74-76 would fall within Invention III – starting materials. As such, Applicants have cancelled Claims 71-76 as being drawn to non-elected subject matter and reserve the right to pursue such subject matter in a divisional application. Verification that Claims 74-76 belong to Invention III is respectfully requested.

Applicants hereby elect the Group I claims (Claims 1-53); consequently, Claims 54-76 have been cancelled as being directed to non-elected subject matter.

Support for new Claim 77 may be found in the originally filed Claim 52. Support for new Claims 78-81 may be found on page 18, line 29 – page 19, line 2 of the specification and Example 20 on pages 140-141 of the specification.

Claims 1, 2, 4, 5, 6, 11, 20, 22, 36, and 38 were amended to insert the term “chemical” in front of the term “moiety.” This amendment is for purposes of clarity as discussed below and does not change the scope of the original claims.

Claims 1 and 43 were amended to insert the phrase “where said 4- to 6-membered heterocycle contains....” This amendment is for purposes of clarity as discussed below and does not change the scope of the original claims.

Claim 53 was amended to remove the phrase “or an analog thereof.” Reasons for this amendment are discussed below.

§112 Rejections

I. Claims 1-9, 11-17, 20-25, 27-33, 36-41, 43-48 and 50-53 were rejected under 35 USC §112, 2nd paragraph as being indefinite.

(1) Examiner objected to the use of the terms “or” and “and” in a Markush expression for the variable R^{4d}. Applicants respectfully disagrees that the use of the

terms is unclear in the context of the claims. Applicant has reproduced that portion of the claim and introduced indentations to clarify how the elements interact.

"R^{4d} and R^{4d'} are each independently

hydrogen,

cyano,

hydroxy,

amino,

H₂NC(O)-, or

a chemical moiety selected from the group consisting of (C₁-C₆)alkyl, (C₁-C₆)alkoxy, acyloxy, acyl, (C₁-C₃)alkyl-O-C(O)-, (C₁-C₄)alkyl-NH-C(O)-, ((C₁-C₄)alkyl)₂N-C(O)-, HO-NH-, (C₁-C₆)alkylamino-, di(C₁-C₄)alkylamino-, (C₃-C₆)cycloalkylamino-, acylamino-, aryl(C₁-C₄)alkylamino-, heteroaryl(C₁-C₄)alkylamino-, aryl, heteroaryl, a partially or fully saturated 3- to 6-membered heterocycle, and a partially or fully saturated 3- to 8-membered carbocyclic ring, where *said chemical moiety* is optionally substituted," (emphasis added)

Unlike hydrogen, cyano, hydroxy, amino, and H₂NC(O)-, the chemical moieties in the list may be optionally substituted. The phrase "said chemical moiety" clearly refers back to the chemical moiety and not the other variables. As agreed upon with the Examiner, Applicant added the term "chemical" to make it perfectly clear that the phrase optionally substituted refers back to the chemical groups in the list of chemical moieties and not the other variables.

For each instance where chemical moiety is used in the definition of the claims, the term "chemical" was inserted to remove any ambiguity.

(2) Secondly, Examiner asserts that the phrase "R⁵ and R⁷ taken together form a 5- or 6-membered lactone, 4- to 6-membered lactam, or a partially or fully saturated 4- to 6-membered heterocycle containing 1 to 2 heteroatoms independently selected from oxygen, sulfur or nitrogen" is unclear with respect to what group contains the 1 to 2 heteroatoms. Applicant has amended Claims 1 and 43 to introduce the phrase "where said 4- to 6-membered heterocycle contains 1 to 2 heteroatoms independently selected

from oxygen, sulfur or nitrogen,” to make it clear that the 1 to 2 heteroatoms refers to the 4- to 6-membered heterocycle and not the lactone or lactam. Examiner agreed in the interview that the amendment to Claims 1 and 43 renders this rejection moot.

(3) Thirdly, Examiner objected to the use of the term “analog” in reference to PYY₃₋₃₆. As pointed out to the Examiner, specific references are provided to illustrate representative examples of PYY₃₋₃₆ and its analogs that would be useful in the practice of the present invention. See page 53, lines 7-9 of the specification (e.g., reference to US Publication No. 2002/0141985 and WO 03/027637). Since the claims are read in light of the specification, the specification provides more than ample description of what Applicant means by the term PYY₃₋₃₆ (including the analogs thereof) without inclusion of every permutation of the term in the claims which would make the claims very lengthy and difficult to read. Consequently, Applicant considers the meaning of PYY₃₋₃₆ to be inclusive of those derivatives within the current state of the art, in particular, those derivatives discussed in the references incorporated by reference on page 53, lines 7-9. As agreed upon with the Examiner, Applicant has removed the reference to analog in Claim 53.

II. Claims 1-53 were rejected under 35 USC §112, 1st paragraph for lack of enablement for making and using solvates.

Examiner asserts that, although enabling for other forms, the specification is not adequately enabled as to how to make solvates/hydrates of the compounds of present invention and that examples of solvates and/or hydrates need to be disclosed.

Examiner asserted that the Examples failed to produce a solvate or hydrate; therefore, no evidence that such species exists. This is not necessarily true. The analytical data disclosed in the specification would not detect whether or not a solvate or hydrate had actually formed. Applicant has attached hereto evidence that compounds of the present invention are capable of forming solvates/hydrates. In particular, a declaration by Stephen R. Anderson establishes and evidences that the hydrochloride salt of 1-[9-(4-chloro-phenyl)-8-(2-chloro-phenyl)-9H-purin-6-yl]-4-ethylamino-piperidine-4-carboxylic acid amide (Example 20A-1) forms a hydrate using procedures well-known in the art.

The preparation of solvates of organic compounds is routine in the art as

evidenced by Polymorphism in Pharmaceutical Solids, Ed. Harry G. Brittan, Vol 95, Marcel Dekker, Inc., New York, 1999 (referred to herein as "Brittan reference"). For example, Chapter 5 entitled "Generation of Polymorphs, Hydrates, Solvates and Amorphous Solids" on pages 202-208 of the Brittan reference (attached hereto) describes how solvates of both organic and inorganic compounds are routinely prepared. In addition, methods for the characterization of such forms are also discussed. Since it is well established in the law that a specification is not required to include routine processes for enablement, Applicant respectfully submits that the attached evidence showing that a hydrate/solvate can be formed in conjunction with the knowledge of the skilled artisan renders this rejection moot.

Specification

I. *The abstract was objected to as being too vague.*


Applicant respectfully submits that the amendment to the abstract renders this objection moot.

Based on the amendments to the Claims and the arguments provided above, Applicant respectfully submits that Claims 1-53 and new Claims 77-81 are in condition for allowance.

Respectfully Submitted:

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